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Considerations from the Brazilian Council of Ophthalmology (CBO) Health Insurance Committee regarding Antiangiogenic Treatment

Considerações da comissão de saúde suplementar do CBO sobre o tratamento com anti-angiogênicos

Consideraciones del Comité de seguros de salud de la CBO sobre el tratamiento con anti-angiogénico

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In this report, the Brazilian Council of Ophthalmology (CBO) Health Insurance Committee offers some considerations regarding ocular chemotherapy treatment with antiangiogenics.

The code provided by the Brazilian Hierarchical Classification of Medical Procedures (CBHPM) for this procedure is 3.03.07.14-7 "Ocular chemotherapy treatment with antiangiogenics - 24-Month Program - One session per month (per session)." In this hierarchical classification, the following complementary information is included: Code No. 3.03.07.14-7 allows for the procedure to be performed in a sterile environment (operating room); short-term hospitalization is not included; fees, materials, and medications are not included.

From this, it is clear that this type of practice does not have legal support in Brazil, although the procedure is widely performed in medical offices in the US. Therefore, medical practitioners who go against this law without due cause are subject to the penalties outlined in the current legislation.

Some procedures, including less invasive procedures that are essentially characterized as "outpatient procedures," are currently performed not only on hospitalized patients but also on patients who receive what is referred to as "short-term hospitalization." Nevertheless, we should clarify that the expression "outpatient surgery" is inadequate, because the outpatient is defined with respect to the patient. The extent of the surgical procedure would be the same, whether the patient is hospitalized or not. In practice, things do not always work that way. In many situations, hospitalization in a day hospital or short-term hospitalization for an ophthalmology procedure is claimed to be necessary. In reality, however, the procedures end up being performed in a clinical setting in which not even a hospital bed is made available for patients' post-operative recovery. These patients are immediately released after the procedure. This practice goes against the concept described above and should be avoided at all costs.

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Day hospitals should therefore be seen as an intermediary option between hospitalization and outpatient care. To perform these clinical, surgical, diagnostic, and therapeutic procedures, this option is recommended when the patient is required to remain under observation for a maximum period of 12 hours (Ordinance No. 44/GM/2001).

These concepts are detailed in the Brazilian Federal Medical Council (CFM) Resolution No. 1886/2008, which revokes CFM Resolution No. 1.409/94 and establishes "Minimum standards for the operation of medical offices and surgical centers for short-stay procedures." Thus, we saw a replacement of the term "outpatient surgeries" with "short-stay procedures" in order to avoid incorrect interpretations. It has also been proposed that, with the exception of a type I surgery, all other types of surgery should be performed in locations that are properly prepared for surgeries.

The current resolution is based on three main points:

I - Classifications of the establishments into type I to type IV units:

a) sanitary structural conditions in the surgical center and the means necessary to sterilize/disinfect surgical instruments according to current laws;

b) records of all procedures performed;

c) minimum conditions for anesthetic practices as per CFM Resolution No. 1802/2006;

d) the guarantee of hospital support in cases that may require intervention, whether in the medical practitioner's own establishment or through an agreement with a hospital; and

e) the guarantee of 24-hour assistance for any possible complications after patients are discharged, whether in the medical practitioner's own establishment or through an agreement with a hospital.

II - Criteria for the selection of patients who may undergo a surgery with short-term hospitalization are as follows:

a) patient lacks any systemic impairments, whether caused by other diseases or by the surgical disease, and patient lacks moderate systemic disorders from any general disease;

b) surgical procedures that do not require special post-operative care; and

c) the demand for a lucid and previously identified accompanying adult.

III - Conditions for the patient's release from the short-stay hospital include:

a) awareness of time and space;

b) stable vital signs;

c) absence of nausea and vomiting;

d) absence of difficulty in breathing;

e) ability to ingest fluids;

f) ability to move around as before, if the surgery allows;

g) minimal or no bleeding;

h) no signs of urinary retention; and

i) Knowledge must be given to the patient and the accompanying adult either verbally or in writing regarding the instructions for post-anesthetic and post-operative care, as well as instructions for the patient to receive care for any possible complications.

CFM Resolution No. 1886/2008 also states that all clinical surgical procedures (with the exception of those that are related to births) that require the patient's overnight stay because of the extent of the procedure shall be considered as surgeries with short-stay hospitalization. Occassionally, an unplanned overnight stay may be necessary; therefore, to be considered as a short stay, the patient's stay in the facility should not exceed 24 hours.

Meanwhile, anesthesia for short-stay surgeries is correlated with all anesthesia procedures that allow for the patient's immediate or rapid recovery, without the need for an overnight stay except for some occasional cases. The types of anesthesia that allow for the patient's rapid recovery include local anesthesia with or without sedation and general anesthesia with rapid elimination.

In addition, the legal document classifies the health care establishments that perform short-stay clinical surgical procedures using the following system:

a. Type I Unit;
b. Type II Unit;
c. Type III Unit; and
d. Type IV Unit.

The proposal of this conceptual report is to attempt to clarify information and to alert fellow ophthalmologists about the possible legal implications specifically associated with pharmacomodulation procedures that involve the use of antiangiogenic drugs. After examining the content of CFM Resolution No. 1.886/2008, we report that the document allows for this type of procedure and the categorization of the unit as a type II unit with the possibility of short-stay hospitalization.

Below text includes the characterization of mentioned facility based on subsection 2.1.2 of the aforementioned resolution:

2.1.2 Type II Unit

a. A Type II Unit is a health care facility independent from a hospital and established to perform minor and intermediate surgical procedures with the means to offer short-stay hospitalization in operating rooms that are adequate for this purpose;
b. The facility must include recovery or observation rooms for patients;
c. The facility must perform minor and intermediate surgical procedures under locoregional anesthesia (with the exception of spinal and epidural blockade) with or without sedation;
d. When necessary, overnight stays should take place at supporting hospital; and
e. The facility is obligated to guarantee a supporting hospital of reference.

Meanwhile, in item 5. "Necessary Materials", Subsection 5.2, the resolution outlines that Type II Units should possess the following materials:

a. surgical instruments;
b. suction tubes;
c. an emergency kit equipped with emergency medication and cardiopulmonary resuscitation (CPR) equipment;
d. an oxygen source;
e. equipment that provides adequate lighting for the surgical field;
f. an adequate operating table/gurney for performing surgeries;
g. specific equipment for practiced medical specialty (such as surgical microscopes);
h. a sterilizer/autoclave for sterilizing material if necessary;
i. locked equipment for medication that requires special monitoring;
j. a tensiometer or sphygmomanometer;
k. equipment for cardiac auscultation;
l. a cabinet with a door or another protective device for sterilized and disposable material;
m. hospital-grade furnishings for patient use (only this type of furnishing shall be permitted);
n. adequately sterilized material according to current legislation;
o. waste collection materials according to the Brazilian Technical Standards Association (ABNT);
p. a pulse oximeter; and
q. other auxiliary equipment required for specialty.

The CBO Health Insurance Committee is available to answer any questions that the CBO members might have regarding this topic.



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